Exhibit 9

United States of America ex rel. Ven-a-Care of the Florida Keys, Inc. v. Abbott Laboratories, Inc., et al.,
Civil Action No. 01-12257-PBS

Exhibit to the July 24, 2009, Declaration of George B. Henderson, II
In Support of United States' Common Memorandum of Law in Support of Cross-Motions for Partial Summary Judgment and in Opposition to the Defendants' Motions for Summary Judgment

MEDICARE PAYMENTS FOR CURRENTLY COVERED PRESCRIPTION DRUGS

HEARING

BEFORE THE

SUBCOMMITTEE ON HEALTH

OF THE

COMMITTEE ON WAYS AND MEANS
HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

SECOND SESSION

OCTOBER 3, 2002

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MEDICARE PAYMENTS FOR CURRENTLY COVERED PRESCRIPTION DRUGS

THURSDAY, OCTOBER 3, 2002

HOUSE OF REPRESENTATIVES,
COMMITTEE ON WAYS AND MEANS,
SUBCOMMITTEE ON HEALTH,
Washington, DC.

The Subcommittee met, pursuant to notice, at 10:38 a.m., in room 1100 Longworth House Office Building, Hon. Nancy L. Johnson (Chairman of the Subcommittee) presiding.

[The advisory announcing the hearing follows:]

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE
September 26, 2002
No. HL–18

CONTACT: (202) 225–3943

Johnson Announces Hearing on Medicare Payments for Currently Covered Prescription Drugs

Congresswoman Nancy L. Johnson (R–CT), Chairman, Subcommittee on Health of the Committee on Ways and Means, today announced that the Subcommittee will hold a hearing on pricing mechanisms for drugs covered under the Medicare program. In addition, the hearing will examine physician reimbursement for administration of these prescription drugs. **The hearing will take place on Thursday, October 3, 2002, in the main Committee hearing room, 1100 Longworth House Office Building, beginning at 10:00 a.m.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from invited witnesses only. Witnesses will include the Administrator of the Centers for Medicare and Medicaid Services (CMS), academics, and providers. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

Medicare does not cover most outpatient prescription drugs. However, it does cover certain categories of outpatient prescription drugs, including drugs used in dialysis, organ transplantation, cancer treatment, and certain drugs used with durable medical equipment, such as infusion pumps and nebulizers. According to the U.S. General Accounting Office, about 450 outpatient drugs are covered under these categories. Medicare payments for covered drugs have skyrocketed, increasing beneficiary and taxpayer costs, and driving potentially inappropriate clinical decisions.

In 1992, Medicare paid about $700 million for prescription drugs; eight years later, it paid $5 billion. (Between 1999 and 2000, payments increased by $1 billion.) In addition, just 35 drugs account for 82 percent of Medicare spending and 95 percent of the claims volume.

The Balanced Budget Act of 1997 (P.L. 105–33) specified that Medicare payment for covered outpatient prescription drugs would equal 95 percent of the average wholesale price (AWP) for the drug. AWPs, however, are not defined by law or regulation. The AWPs are reported by drug manufacturers to organizations that publish the data in compendia. Medicare carriers use the published data in calculating payment for Medicare covered drugs, but AWPs are not grounded in any real market transaction, and do not reflect the actual price paid by purchasers. The AWP for a product is often far greater than the acquisition cost paid by suppliers and physicians. In addition, AWPs do not reflect the discounts, rebates or "charge backs" that manufacturers and wholesalers customarily offer to providers. Therefore, AWPs represent neither average prices nor prices charged by wholesalers.

Medicare pays an excessive amount for covered drugs. The U.S. Department of Health and Human Services Inspector General found that Medicare beneficiaries and taxpayers could save more than $200 million on one drug alone—albuterol, an inhalation therapy drug—if the drug were reimbursed at prices available to commercial purchasers. Moreover, a higher AWP creates a higher beneficiary copayment and premium, because beneficiaries are responsible for a copayment equal to 20 percent of Medicare's payment for the drug. In some cases, the beneficiary's copayment is greater than the physician's or supplier's actual total cost for the drug.

Some manufacturers reportedly use inflated AWPs as a strategy to increase market share. Physicians and suppliers are reimbursed based on the inflated AWP, but actually pay much less to acquire the drug. The larger the "spread" between the actual price and 95 percent of the AWP, the greater the incentive to use the product. This inappropriately influences clinical decisions and may harm patient care, while driving over-utilization of services.

Some physicians have expressed concerns about lowering Medicare reimbursements for prescription drugs. They assert that they are under-reimbursed by Medicare for their costs in administering the drugs, and claim that the overpayments for drugs to cover their practice expenses. Oncologists, for example, argue that Medicare does not adequately reimburse them for the practice expenses associated with providing treatment to cancer patients in outpatient settings.

There is little rationale for using Medicare overpayment for drugs as a mechanism to reimburse physicians for practice expenses. Medicare has a well-defined procedure for examining the adequacy of physician payments under the physician fee schedule. As provided for under the Benefits Improvement and Protection Act, oncologists recently submitted results from a new survey on practice expenses to CMS as part of this review. Because any increase in practice expense reimbursements to one specialty, such as oncology, must be budget neutral under current law, other specialties would experience decreases in their practice expenses, unless Congress were to provide new money to recognize these practice costs.

In announcing the hearing, Chairman Johnson stated, "The AWP process is seriously flawed. It's costing Medicare beneficiaries and taxpayers too much because Medicare is paying inflated prices. We must inject competition into the program to bring market forces to bear on reimbursement for drugs. The Administration says that they will fix the problem if Congress does not act, but it will take congressional action to ensure that our seniors continue to have access to high-quality cancer care."

FOCUS OF THE HEARING:

Thursday's hearing will highlight problems with the AWP system for determining Medicare reimbursements for currently covered prescription drugs, and examine alternative mechanisms for determining Medicare payments.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Due to the change in House mail policy, any person or organization wishing to submit a written statement for the printed record of the hearing should send it electronically to *hearingclerks.waysandmeans@mail.house.gov*, along with a fax copy to (202) 225–2610, by the close of business, Thursday, October 17, 2002. Those filing written statements who wish to have their statements distributed to the press and interested public at the hearing should deliver their 200 copies to the Subcommittee on Health in room 1136 Longworth House Office Building, in an open and searchable package 48 hours before the hearing. The U.S. Capitol Police will refuse sealed-packaged deliveries to all House Office Buildings.

FORMATTING REQUIREMENTS:

Each statement presented for printing to the Committee by a witness, any written statement or exhibit submitted for the printed record or any written comments in response to a request for written comments must conform to the guidelines listed below. Any statement or exhibit not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. Due to the change in House mail policy, all statements and any accompanying exhibits for printing must be submitted electronically to *hearingclerks.waysandmeans@mail.house.gov*, along with a fax copy to (202) 225–2610, in Word Perfect or MS Word format and MUST NOT exceed a total of 10 pages including attachments. Witnesses are advised that the Committee will rely on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. Any statements must include a list of all clients, persons, or organizations on whose behalf the witness appears. A supplemental sheet must accompany each statement listing the name, company, address, telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at http://waysandmeans.house.gov.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call (202) 225–1721 or (202) 226–3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.

Chairman JOHNSON. Good morning. This morning's hearing is very important in our effort to strengthen our Medicare Program. The evidence is overwhelming that Medicare is paying way too much for some items of durable medical equipment (DME) and prescription drugs. It is imperative that we adopt a system that more accurately aligns costs and payments.

While this would not normally be a difficult task, it is a very difficult problem at this time because most cancer care is paid for through drug reimbursements. This means that as we change the way we pay for drugs, we must also realistically and accurately reimburse for the practice expenses associated with the delivery of, for example, chemotherapy. These practice expenses are significant—personnel, special equipment, costly drug inventories and insurance to cover them, and so forth.

So assuring reimbursement for practice expense is no easy task, yet it has been only a minor part of the average wholesale price (AWP) discussion. The U.S. General Accounting Office (GAO) tried identifying practice expenses, but neglected to focus its work appropriately on oncologists who deliver such care in an office setting. The oncology community was slow, as well, to rise to this quite daunting task.

However, now we are developing the needed information. Today we are unified in our quest to change the way we pay for Medicare-covered drugs and the way we pay for the costs of administering those drugs.

While I am keenly disappointed in the GAO study, I am pleased that the oncologists have taken advantage of a provision I wrote in the Benefit Improvement and Protection Act. The provision permits groups to submit practice expense data and requires the Centers for Medicare & Medicaid Services (CMS) to evaluate that data and use it if it meets certain standards. The most recent data is very important and particularly significant because of our earlier failure to collect appropriate information.

Overpaying for drugs burdens seniors with copayments that in some instances exceed the cost paid for the drug by the physician, pharmacist, or provider of durable medical equipment. On the other hand, underpayment will, without question, deny seniors access to life-saving care.

Medicare spending on part B drugs is very concentrated. Just 35 drugs account for 82 percent of Medicare spending, and 95 percent of the claims volume. Furthermore, Medicare payments for covered drugs have skyrocketed, increasing beneficiary and taxpayer costs. In 1992, Medicaid paid about $700 million for prescription drugs. In 2000, it paid $5 billion, a 700-percent increase over 8 years.

Medicare's payment for these drugs is prescribed in law. The Balanced Budget Act 1997 specifies that Medicare pay 95 percent of the AWP, for the drug. The AWPs, however, are not defined by law or regulation. They are reported by drug manufacturers to or-

ganizations that publish the data in compendia, like the Red Book. Medicare carriers use the published data to calculate payment.

The problem is that AWPs do not reflect the actual price paid by purchasers. Nor do they accurately account for the costs associated with administering the drugs, for which no other Medicare payment is made. The AWPs are often far greater because they do not reflect the discounts, rebates, or so-called charge backs that manufacturers and wholesalers customarily offer to providers. On the other hand, for cancer drugs, they have the costs of inventory, insurance, special equipment, nursing, and other personnel that are not captured in any other payment.

Examples of overpayment abound, forcing seniors to bear higher copayments and premiums. Beneficiaries pay a copayment equal to 20 percent of Medicare's payment for the drug. For some drugs, beneficiaries are, indeed, paying more in copayments than physicians or suppliers are paying to purchase the drug.

Consider Vancomycin, with an AWP of $382. The beneficiary would pay 20 percent, or $73. The provider would pay $5, on average. That is a $73 payment by the beneficiary for a drug that cost the provider $5.

Here are just a few examples comparing one company's 2001 AWP, as reported in the Red Book, and the actual wholesale prices determined by the U.S. Department of Justice. Vancomycin, the Red Book reported AWP was $382 compared to the U.S. Department of Justice actual price of $5, an injectable drug. The other two are also injectable. In the interests of time, I am going to skip over the details.

A second and equally serious problem are reports that some manufacturers use inflated AWPs as a strategy to increase market share. If Medicare reimburses physicians and suppliers based on the inflated AWP, providers have a greater incentive to use the products with the larger spread. Providers may base prescribing decisions on economic incentives rather than clinical appropriateness. This practice may harm patient care and drive over-utilization of services.

Of all countries, America has the greatest access to cancer care. In recent years, there has been a revolution in cancer care, enabling physicians to deliver the latest in quality care in many small centers across America. Medicare does not reimburse oncologists for the practice expenses associated with providing treatment to cancer patients in outpatient settings. Consequently, they have come to rely on the overpayment for drugs to cover these costs.

Before we eliminate overpayments, we must assure appropriate reimbursement for practice expenses. While all agree on this, I am determined it be done accurately and fairly. I am disappointed with the relatively small amount of attention that has been focused on this issue and will pursue it in questioning.

We are very pleased to welcome the Honorable Thomas A. Scully from the Centers for Medicare & Medicaid Services again before us, and on our second panel, George Reeb, Michael J. O'Grady, Ph.D., Paul A. Bunn, Jr., M.D., John D. Jones, and Kim Glaun, whom I will introduce a little bit more at a later time. Mr. Stark?

[The opening statement of Chairman Johnson follows:]

Opening Statement of the Hon. Nancy L. Johnson, a Representative in Congress from the State of Connecticut, and Chairwoman, Subcommittee on Health

Good morning. This morning's hearing is a very important one in our effort to strengthen our Medicare program. The evidence is overwhelming that Medicare is paying way too much for some items of durable medical equipment and prescription drugs. It is imperative that we adopt a system that more accurately aligns costs and payments.

While this would not normally be a difficult task, it is a very difficult problem at this time because most cancer care is paid for through drug reimbursements. That means that as we change the way we pay for drugs, we must also realistically and accurately reimburse for the practice expenses associated with the delivery of, for example, chemotherapy, and these practice expenses are significant, personnel, special equipment, costly drug inventories, and the insurance to cover them and so forth.

So assuring reimbursement for practice expense is no easy task, yet it has been only a minor part of the AWP discussion.

The GAO tried identifying practice expenses but neglected to focus its work appropriately on oncologists who deliver such care in an office setting. The oncology community was slow as well to rise to this quite daunting task. Now, however, we are developing the needed information and today, are unified in our quest to change the way we pay for Medicare-covered drugs . . . and the way we pay for the costs of administering those drugs.

While I am keenly disappointed in the GAO study, I am pleased that oncologists have taken advantage of a provision that I wrote in the Benefit Improvement and Protection Act that permits groups to submit practice expense data and requires the Centers for Medicare and Medicaid Services to evaluate that data and use it, if it meets certain standards. Their most recent data is very important and particularly significant because GAO failed to collect appropriate data in the study we sought for that purpose, though unintentionally.

Overpaying for drugs burdens seniors with co-payments that in some instances exceed the cost paid for the drug by the physician, pharmacist, or provider of durable medical equipment. On the other hand, underpayment will without question deny seniors access to life-saving care.

Medicare spending on Part B drugs is very concentrated: just 35 drugs account for 82 percent of Medicare spending and 95 percent of the claims volume.

Furthermore, Medicare payments for covered drugs have skyrocketed, increasing beneficiary and taxpayer costs. In 1992, Medicare paid about $700 million for prescription drugs; in 2000, it paid $5 billion, a 700 percent increase over 8 years, though the number of drugs used has soared as well.

Medicare's payment for these drugs is prescribed in law. The Balanced Budget Act of 1997 specifies that Medicare pay 95 percent of the average wholesale price, or AWP, for the drug. AWPs, however, are not defined by law or regulation. They are reported by drug manufacturers to organizations that publish the data in compendia, like the Red Book. Medicare carriers use the published data to calculate payment.

The problem is that AWPs do not reflect the actual price paid by purchasers, nor do they accurately account for the costs associated with administering the drugs, for which no other Medicare payment is made. The AWPs are often far greater because they do not reflect the discounts, rebates or so-called "charge backs" that manufacturers and wholesalers customarily offer to providers. On the other hand, for cancer drugs, the heavy costs of inventory, insurance, special equipment, nursing and other personnel are not captured by any other payment.

Examples of overpayment abound, forcing seniors to bear higher copayments and premiums. Beneficiaries pay a copayment equal to 20 percent of Medicare's payment for the drug. For some drugs, beneficiaries are paying more in copayments than physicians or suppliers are paying to purchase the drug.

Consider vancomycin, with an AWP of $382. The beneficiary would pay 20 percent of the Medicare reimbursement of $363, or $73. The provider would pay about $5, on average. That's a $73 payment by the beneficiary for a drug that costs the provider $5.

A second and equally serious problem are reports that some manufacturers use inflated AWPs as a strategy to increase market share. If Medicare reimburses physicians and suppliers based on the inflated AWP, providers have a greater incentive to use products with a larger "spread" between the actual price they pay and Medicare's reimbursement. Providers may base prescribing decisions on economic incen-

tives rather than clinical appropriateness. This practice may harm patient care, and drive over-utilization of services.

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We are pleased to welcome Tom Scully from the Centers for Medicare and Medicaid Services who will give us his views on AWP reform.

Our second panel will include:

- George Reeb, from the Office of the Inspector General in the Department of Health and Human Services will update us on his findings comparing AWP to actual acquisition costs;
- Michael O'Grady from Project Hope will discuss a competitive bidding approach to establishing Medicare reimbursements for outpatient drugs;
- Dr. Paul Bunn from the American Society of Clinical Oncology will tell us about the new information on practice expenses that the Society has collected and submitted for consideration; and
- Kim Glaun from the Medicare Rights Center will present concerns from beneficiaries perspective.

I look forward to your testimony.

Mr. STARK. Thank you, Chairman Johnson, for holding this hearing today. I could not agree with you more. It is clear that the pharmaceutical industry, and its partners are bilking Medicare beneficiaries and the program, perhaps out of billions of dollars.

I will not repeat many of your observations because they hold. This illegal behavior, I think, harms each and every one of us. Medicare pays more for the services it covers, and the taxpayers pay more, in many cases, or beneficiaries pay more.

The drug companies will argue in their defense that they are operating within the letter of the law. They will not change their behavior unless and until the law changes. Well, I disagree with their interpretation of the law. I certainly will agree with them that they are right. We should change the law, and that will take care of that.

I have introduced a bill which would end the outrage. It is a market-based solution which would require Medicare to pay the true average market price for the drugs currently covered. That means we pay for what the doctors or the hospitals actually pay. It is consistent with the GAO recommendations. It is achievable in a short timeframe. It is enforceable, very stiff penalties, and it also recognizes that we must address the inadequacies of the current reimbursement to the doctors.

One of the reasons this is so prevalent is that the doctors feel they are underpaid for the administration. They make it up through marking up the drugs. I do not think that is the way to do it. I think if they are underpaid, we should address that, as well. Then we will have a solution.

I would like to put some human terms on this. There is an enterprising person in Florida. I know this sounds like a little advertising, but that is okay. He looked up on the web—he was mad about this problem and found my bill. He wrote to one of our staff